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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/585,645	06/01/2000	Huda Y. Zoghbi	P01899US2	4965

26271 7590 10/20/2003
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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/585,645

Applicant(s)

ZOGHBI ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-46, 48, 112-114, 117-119, 121, 123 and 124 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☒ Claim(s) 40-46, 48, 112-114, 117-119 and 124 is/are allowed.

- 6) ☒ Claim(s) 121 and 123 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 September 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 29.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 30. 6) ☐ Other:

DETAILED ACTION

Claims 40-46, 48, 112-114, 117-119, 121, 123 and 124 are pending in the application.

This Office Action is in response to the Amendment filed on 7/29/03.

Response to Amendment

The objection to claims 40-48, 112-119, 121, 123 and 124 has been withdrawn in light of Applicants' arguments.

The rejection of claims 40-48, 112-119 and 124 under 35 U.S.C. 112 1st paragraph has been withdrawn in light of Applicants' arguments and submission of relevant references.

Claims 121 and 123 are rejected under 35 U.S.C. 112 1st paragraph for reasons discussed below.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 121 and 123 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid sequence encoding a fusion protein comprising an atonal-associated nucleic acid and an additional nucleic acid encoding a tag for purification of the protein, does not reasonably provide enablement for a nucleic acid or composition comprising an atonal-associated nucleic acid and any other kind of nucleic acid.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The nature of the invention is a nucleic acid sequence encoding a fusion protein comprising an atonal-associated amino acid sequence and a desired amino acid sequence. The

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claims are further drawn to a composition comprising an atonal-associated sequence, a delivery vehicle and an additional nucleic acid sequence which is not an atonal-associated sequence.

The scope of the claims encompasses a nucleic acid sequence encoding a fusion protein comprising an atonal-associated amino acid and any protein of interest, or a composition comprising an atonal-associated nucleic acid and any other nucleic acid. Such scope exceeds the scope that is supported by the instant specification.

The teaching of the specification is limited. The specification only teaches that Math1, an ortholog of atonal gene, is responsible for inner ear hair cell development in mouse. The specification fails to disclose any fusion protein of Math1 or other atonal-associated nucleic acid that would generate inner ear hair cell. The specification also fails to teach a composition comprising an atonal associated nucleic acid and an additional nucleic acid that has hair cell generating activity. The specification merely discloses that a fusion protein such as a tag would be useful in purifying protein encoded by atonal associated nucleic acid. As such, the claim is enabled only for this embodiment.

The state of art at the time of filing is silent on a fusion protein encoded by atonal associated nucleic acid and other sequences. Therefore, one skilled in the art would have to rely solely on the guidance provided in the specification to make and use the invention to its full scope. As discussed above, the specification only supports a fusion protein encoded by atonal-associated nucleic acid and a tag for purification purpose. One skilled the art would have to engage in undue experimentation to use the invention to its full scope. Therefore, the claims are not enabled.

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Claims 40-46, 48, 112-114, 117-119 and 124 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER